

## **REMARKS**

### **I. INTRODUCTION**

Claims 1-7, 14, 16-22, 29, 31-37 and 45-51 are pending in the present application. Claim 59 has been added. Support for claim 59 may be found throughout the specification, and particularly in, for example, p. 14, l. 11 – p. 16, l. 12. No new matter has been added.

### **II. CLAIM REJECTIONS UNDER 35 U.S.C. § 112**

Claims 1, 16, 31-37 and 45-51 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner maintains the position that these claims contain new matter, namely the recitation of various proteins that confer insect resistance in plants: Cry2, Cry9, and Vip3A. Final Office Action, pp. 2-4. The Examiner takes the position that Applicant's statement that all patents and other references are incorporated by reference in their entirety is ineffective because it does not constitute a "specific indication of what material is being incorporated." Final Office Action, p. 4. Because the specification does not contain a "specific mention" that information regarding Cry2, Cry9, and Vip3A are incorporated by reference, the Examiner takes the position that references to these proteins are new matter. *Id.* Applicant respectfully traverses these rejections.

The Examiner has incorrectly applied the law in determining the relevant disclosure has not been incorporated by reference. The specific reference in the specification to what is incorporated is exactly what Applicant pointed out in the previous response, namely that all patents referenced in the specification are incorporated by reference as if each were specifically indicated to be incorporated by reference. *See* Specification, p. 20, ll. 21-24. The Federal Circuit has observed that such a statement effectively incorporates the referred-to material by reference. *See, e.g., LG Elecs., Inc. v. Bizcom Elecs., Inc.*, 453 F.3d 1364, 1374 & n.3 (Fed. Cir. 2006) (observing the statement "herein incorporated by reference in [their] entirety" in the specification resulted in the external document to be "incorporated" into the specification), *rev'd on other grounds sub nom., Quanta Computer, Inc. v. LG Elecs., Inc.*, 128 S. Ct. 2109 (2008).

The MPEP states material in publications or patents incorporated by reference "is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed." *See* MPEP § 2163.07(b). The fact that the

specific context in which the relevant patents are referred to in the specification is not the purpose for which they are being referred to for here has no bearing on the relevant question. As shown above, the incorporation by reference was effective under Federal Circuit law and the MPEP. As a result, as set forth in the MPEP, the disclosures of the relevant patents "should be treated as part of the text of the application as filed." *Id.* As such, the references to Cry2, Cry9, and Vip3A from these patents are part of the text of the application as filed. *Id.* Therefore, the references to these proteins in the claims cannot constitute new matter, and the written description rejection is improper.

### **III. CLAIM REJECTIONS UNDER 35 U.S.C. § 103**

#### **A. Rejection of Claims 1, 4, 16, and 19 over Zhao**

Claims 1, 4, 16 and 19 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Zhao *et al.* (2003, Nature Biotechnol. 21:1493-1497). Final Office Action, pp. 5-6. Specifically, the Examiner maintains that because Zhao states there is no linkage between Cry1Ac and Cry1C resistance in diamondback moths, Cry1Ac and Cry1C operate via different modes of action. *Id.* Further, although the Examiner admits Zhao does not teach planting a blend of seeds of the plants, the Examiner states these claims would be obvious, asserting one in the art "would have been motivated to do so because seeds are what farmers would plant in the fields." *Id.* p. 6. Finally, the Examiner states that Zhao does not teach away from the claimed method "because Zhao does not teach that it should never be used," and that one in the art may use the claimed method "in studies of delaying insect resistance evolution, at least as a comparison to other methods." *Id.* Applicant respectfully traverses this rejection.

The Examiner has ignored the law regarding teaching away. Under the MPEP, a reference teaches away from an outcome if it "'criticize[s], discredit[s], or otherwise discourage[s] the solution claimed.'" MPEP § 2145(X)(D)(1) (quoting *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004)). This is exactly what Zhao does: it criticizes and discourages the mixture method in claims 1, 4, 16, and 19. Specifically, Zhao observes there are at least four possible ways to delay resistance in *Bt* crops: (i) non-high dose; (ii) high dose + refuge; (iii) deploying different toxins individually in different varieties [the claimed method]; and (iv) pyramiding, or deploying two or more toxins in a single plant. *See Zhao*, p. 1493, left column,

second paragraph. Of these, Zhao states "the refuge—high dose (ii) and pyramiding (iv) strategies seem most promising." *Id.* Further, Zhao states "allowing the concurrent release of cultivars with the two *Bt* genes in separate plants, each with one *Bt* gene, is not the best way to delay resistance." *Id.* p. 1495, right column, first full paragraph. Zhao concludes that the pyramiding strategy is the strategy that should be pursued, stating:

stacking or pyramiding toxin genes that express toxins with different modes of action or binding characteristics at a "high" dose offers a potential route for achieving longer delays in the development of resistance. We believe that industry should be encouraged to develop such plants for their increased durability for insect management and we suggest that the smaller refuge size required by pyramided toxin plants may be an additional incentive to do so.

*Id.* p. 1496, left column, first full paragraph.

The only reasonable interpretation of these statements is that Zhao criticizes and discourages the claimed method, namely deploying different toxins in different plants. If one alternative is encouraged, the only conceivable interpretation is that the other alternatives are *discouraged*. *Id.* This is precisely the type of statement that constitutes teaching away as described in the MPEP. *See* MPEP § 2145(X)(D)(1). As such, one of ordinary skill in the art would be dissuaded from utilizing the claimed seed blends, given that Zhao characterizes them as inferior to a pyramiding strategy for resistance management. *See* MPEP § 2141.02(V). Further, other references of record also discourage use of the mosaics of Zhao. *See, e.g., Roush, Pestic. Sci.*, 51:328, 330, right column, last full paragraph (1997) ("Mosaics are the **worst way** to deploy two toxicants, potentially resulting in resistance about twice as fast as if they were used on different generation." (emphasis added)). The claims are effectively proceeding against the accepted wisdom in the art, which is also evidence of nonobviousness. *See* MPEP § 2145(X)(D)(3). There is therefore no reason why one of ordinary skill in the art would modify Zhao in the manner suggested by the examiner. Accordingly, Applicant submits the rejection is in error and should be withdrawn.

Even without Zhao's teaching away from the invention, the rejection still fails. These claims require the seeds be planted in a blend. This is not disclosed in Zhao: The only scenario disclosed in Zhao where two different types of seeds are arguably planted together is a mosaic. *See* Zhao, p. 1494 paragraph spanning the columns; Fig. 1. A mosaic is different from a seed

blend. A mosaic (such as described in Zhao) typically involves adjacent fields being planted with different types of seeds so that resistant insects that develop in one field will be susceptible to the insect control mechanism used in the adjacent field, thereby "diluting" the resistance gene. *See, e.g.,* Roush, *supra*, p. 330, right column, last full paragraph. The claimed method, on the other hand, involves a blend of two types of seeds, such that the two types are not planted in any preset blocks in a given plot. Accordingly, Zhao does not teach this element of the claims, and the Examiner has not shown why one in the art would modify Zhao in this manner.

The fact that one in the art would not make this modification is confirmed in at least two ways. First, as described above, the accepted wisdom in the art is that deploying two types of plants with different toxicants was an inferior manner to control the development of resistant pests. Second, there is a vast difference between the behavior of insects and development of resistance in a laboratory setting (such as Zhao) and an actual field setting. *See, e.g.,* US EPA FIFRA Scientific Advisory Panel, May 6, 2009, p. 14 (noting the commonplace nature of differences in results between laboratory and field testing). As shown in Pan *et al.*, previous studies, such as Zhao, incorrectly predicted a faster onset of resistant insects in the context of a blending strategy. In fact, when real-world factors such as adult mating behavior, realistic distribution of beetles in a field, and farmer compliance are considered, a blending strategy unexpectedly provides substantial improvement in delaying onset of resistance. *See* Pan, pp. 8-13; Tables 1-14.

In summary, the prior art specifically discredits and teaches away from the blending strategy of claims 1, 4, 16, and 19. Further, the blending strategy in these claims provides an unexpected benefit over previously-used insect resistance strategies by delaying the onset of resistance further than traditionally-used methods. Accordingly, Applicant respectfully submits these claims are not obvious over Zhao. Applicant respectfully requests reconsideration and withdrawal of this rejection.

B. Rejection of Claims 5 and 20 over Zhao in view of Pershing

Claims 5 and 20 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Zhao as applied to claims 1, 4, 16, and 19, and further in view of Pershing *et al.* (US Patent No. 6,551,962). Specifically, the Examiner combines the previously-discussed application of Zhao with the teaching of Pershing to treat seed transformed to produce a Cry3Bb protein with

pesticidal agents. *See* Final Office Action, pp. 6-7. Applicant respectfully traverses this rejection.

As described above, the rejection of independent claims 1 and 16 is improper and should be withdrawn. As such, the rejection of claims 5 and 20, which depend from claims 1 and 16 respectively, also cannot be supported by the Examiner's rationale regarding Zhao. As such, Applicant respectfully requests this rejection likewise be withdrawn.

C. Rejection of Claims 14 and 29 over Zhao in view of Plaisted

Claims 14 and 29 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Zhao as applied to claims 1, 4, 16, and 19, and further in view of Plaisted *et al.* (1999, US 5,990,395). Specifically, the Examiner combines the previously-discussed application of Zhao with the teaching of Plaisted of plants with a Cry1Ab gene and an EPSPS gene. *See* Final Office Action, pp. 7-8. Applicant respectfully traverses this rejection.

As described above, the rejection of independent claims 1 and 16 is improper and should be withdrawn. As such, the rejection of claims 14 and 29, which depend from claims 1 and 16 respectively, also cannot be supported by the Examiner's rationale regarding Zhao. As such, Applicant respectfully requests this rejection likewise be withdrawn.

D. Rejection of Claims 2-3, 6-7, 17-18, 21-22, 31-37 and 45-51 over Zhao in view of each of Crickmore, Pershing, and Narva

Claims 2-3, 6-7, 17-18, 21-22, 31-37 and 45-51 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Zhao as applied to claims 1, 4, 16, and 19, and further in view of each of Crickmore *et al.* (1998, Microbiol. Mol. Biol. Rev. 62:807-813), Plaisted, Pershing, and Narva *et al.* (WO 97/40162), taken with the evidence of the instant application. Specifically, the Examiner combines the previously-discussed application of Zhao with Crickmore, which teaches the existence of several Cry proteins, Narva, which teaches Cry34Aa1 and Cry35Aa1, Plaisted, which teaches the combination of Cry1Ab or VIP3 with EPSPS, and Pershing which teaches Cry3Bb proteins and treatment with pesticides. *See* Final Office Action, pp. 8-10. Applicant respectfully traverses this rejection.

As described above, the rejection of independent claims 1 and 16 is improper and should be withdrawn. As such, the rejection of claims 2-3, 6-7, 17-18, 21-22, 31-37 and 45-51, which directly or indirectly depend from either claim 1 or 16, also cannot be supported by the

Examiner's rationale regarding Zhao. As such, Applicant respectfully requests this rejection likewise be withdrawn.

Even assuming the Examiner's rationale regarding Zhao is correct, however, the rejection still cannot be maintained. As noted by the Examiner, Crickmore discloses the existence of numerous (over 100) different Cry proteins, with other Cry proteins disclosed in the other cited references. *See* First Office Action, pp. 8-9; Crickmore, p. 809, Table 1. The Examiner states that even though selecting the specific Cry proteins in the various claims would require selecting among these over 100 proteins, the claims are nevertheless obvious because "one of skill in the art would select a toxin combination based on the desired target pests." Final Office Action, p. 10. Of course, there is nothing in Crickmore as to which of the Cry proteins disclosed therein is effective against any particular target pest. As a result, this remains one of the paradigmatic situations where claims are not obvious. As recently stated by the Federal Circuit, a claim is not obvious when:

"what would have been 'obvious to try' would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful."

*In re Kubin*, Slip Op. at 14 (Fed. Cir. Apr. 3, 2009) (quoting *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988)). Contrary to the Examiner's assertion, there is simply no guidance in Crickmore as to which Cry proteins to select among the numerous selections. Further, the Examiner does not point to any guidance in the prior art as to which combinations are likely to be successful. Accordingly, the Federal Circuit has unambiguously held this type of rejection is improper. As such, for at least this additional reason, Applicant respectfully submits the rejection is improper and should be withdrawn.

E. New claim 59

Claim 59 is similarly allowable over the art of record. For example, it depends from claim 1 which, for the reasons discussed previously, was improperly rejected as obvious over Zhao. Claim 59 further distinguishes from Zhao in that it is directed to control of resistance in Coleopteran pests. Zhao is directed to use of Cry proteins in the diamondback moth, a Lepidopteran pest. *See* Zhao, p. 1493. The response of Coleopteran and Lepidopteran pests to

exposure to insect control mechanisms is different. *See, e.g.,* US EPA FIFRA Scientific Advisory Panel, May 6, 2009, p. 10 (describing characteristics of Lepidopteran response to *Bt* crops); p. 22 (noting the differences between rootworm (Coleoptera) and corn borer (Lepidoptera) mating in response to *Bt* crops). Accordingly, one in the art would not expect teachings regarding a Lepidopteran pest, such as in Zhao, to be applicable to a Coleopteran pest, as claimed in new claim 59.

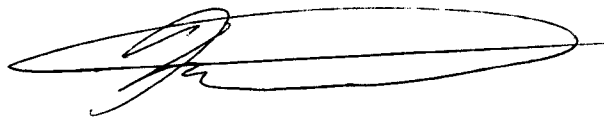
#### IV. CONCLUSION

It is respectfully submitted all matters raised in the Final Office Action have been addressed and remedied and that the application is in form for allowance. Favorable action is respectfully requested.

This amendment accompanies the filing of a Request for Continued Examination (RCE). Please charge Deposit Account No. 26-0084 the amount of \$810.00 for the RCE per the attached transmittal.

This is a request under the provision of 37 CFR § 1.136(a) to extend the period for filing a response in the above-identified application for one month from October 30, 2008 to November 30, 2009. Applicant is a large entity; therefore, please charge Deposit Account number 26-0084 in the amount of \$130.00 to cover the cost of the one month extension. Any deficiency or overpayment should be charged or credited to Deposit Account 26-0084.

Respectfully submitted,



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